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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,350	07/11/2003	John K. Cini	MXI-285RCE2	6687

59819 7590 05/15/2009

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EXAMINER	
LI, RUIXIANG	
ART UNIT	**PAPER NUMBER**
1646	
MAIL DATE	**DELIVERY MODE**
05/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,350	CINI ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/26/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,9-13,15,17-21,23,25,26,29-31,33 and 35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9-13,15,17-21,23,25,26,29-31,33 and 35-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's response filed on 02/26/2009 has been entered. Claims 4, 5, and 27 are canceled. Claims 1, 3, 9-13, 15, 17-21, 23, 25, 26, 29-31, 33, and 35-39 are pending and under consideration.

Claim Rejections under 35 USC § 103 (a)

(i). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(ii). The rejection of claims 1, 3, 9-13, 15, 17-21, 23, 25, 26, 29-31, 33, and 35-39 under 35 U.S.C. 103(a) as being unpatentable over Kerwin et al. (US Patent No. 5,929,031, 27 July 1999), and further in view of Hagiwara et al. (U.S. Patent No. 6,165,467, December 26, 2000), Packer et al. (*Methods in Enzymology,* Volume 186:41-42, 1990), and Akers (*J. Par. Sci. Tech.* 36:222-228, 1982) is maintained. The basis for the rejection is set forth in the previous office action mailed on 12/03/2008.

Applicants argue that Kerwin et al. is completely silent with respect to the use of DEF, let alone at a particular concentration range or in combination with DTPA. Applicants

argue that the teachings of Kerwin et al. cannot be applied to the claimed concentration range of 0.02 mM to 0.5 mM for DEF. Applicants argue that none of the cited references, either alone or in combination, teach or suggest the presently claimed composition, let alone the particularly claimed concentration ranges of DTPA and DEF.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the reasons set forth in the office action mailed on 12/03/2008. With respect to the particular concentration range of DTPA and DEF, Kerwin et al. teach preparation of a pharmaceutical composition comprising chelators, such as 0-200 μM of DTPA and/ or EGTA (lines 45-51 of column 8) and the teachings of Kerwin et al. provide general guide with respect to the use of chelators at the concentration of 0-200 μM. It would have been obvious to one of skilled in the art to follow the teachings of the cited art to prepare a composition formulated with DTPA and DEF at the concentration range of 0-200 μM with a reasonable expectation of success. One would have been motivated to do so because Kerwin et al. teach that one or more chelators at the concentration range of 0-200 μM can be used in a formulation (lines 45-51 of column 8) and Akers teaches that the use of combination of antioxidant in the same formulation produces a synergistic effect (page 227, the 2nd paragraph).

(iii). The rejection of claims 1, 3, 9, 10, 12, 13, 15, 17-21, 23, 25, 26, 29-31, 33, and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US 5,217,954 A, 8 June 1993) in view of Hagiwara et al. (U.S. Patent No. 6,165,467,

December 26, 2000), Packer et al. (*Methods in Enzymology*, Volume 186: 41-42, 1990), and Akers (*J. Par. Sci. Tech.* 36:222-228, 1982) is maintained. The basis for the rejection is set forth in the previous office action mailed on 12/03/2008.

Applicants argue that Foster et al. do not teach or suggest the use of DEF, let alone at a particular concentration range or in combination with DTPA. Applicants argue that none of the cited references, either alone or in combination, teach or suggest the presently claimed composition, let alone the particularly claimed concentration ranges of DTPA and DEF.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the reasons set forth in the office action mailed on 12/03/2008. With respect to the particular concentration range of DTPA and DEF, Foster et al. teach preparation of a pharmaceutical formulation comprising a stabilizing chelator, such as DTPA or EGTA (see, e.g., columns 3-6). Foster et al. teach that the chelators are used individually or in combinations (bottom of column 1 to top of column 2) in amounts of from about 0.001% to about 2.0% percent (weight/weight) of the overall formulation (the 4th paragraph of column 4). Thus, the teachings of Foster et al. provide general guide with respect to the use of chelators at the concentration of from about 0.001% to about 2.0% percent (weight/weight). It would have been obvious to one of skilled in the art to follow the teachings of the cited art to prepare a composition formulated with DTPA and DEF at the concentration range of from about 0.001% to about 2.0% percent (weight/weight)

with a reasonable expectation of success. One would have been motivated to do so because Foster et al. teach that the chelators are used individually or in combinations at the concentration range of from about 0.001% to about 2.0% percent (weight/weight) can be used in a formulation and Akers teaches that the use of combination of antioxidant in the same formulation produces a synergistic effect (page 227, the 2nd paragraph). Since the concentration range of a chelating agent taught by Foster et al. is equivalent to about 0.025 mM to 50 mM for DTPA, and 0.018 to 36 mM for DEF, which overlap with the concentration ranges of DTPA and DEF recited in claims 1 and 27, a prima facie case of obviousness exists (See MPEP 2144.05, Obviousness of Ranges).

Conclusion

No claims are allowed.

Advisory Information

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
May 12, 2009